FUJIFILM
Fujifilm Medical Systems, USA

MAR 2 9 2011

K103596

510(k) Summary
Wireless/Wired FDR D-EVO (DR-ID600 w/DR-ID601SE) Flat Panel Detector System

Date: December 6, 2010

Submitter's Information:

FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, CT, 06902, USA

Contact Person:

Name:	Katherine Y. Choi, RAC
Title:	Regulatory Affairs Specialist
Telephone:	(203) 602-3568
Facsimile:	(203) 363-3950

Identification of the Proposed Device:

Proprietary/Trade Name:	Wireless/Wired FDR D-EVO Flat Panel Detector System (DR-ID600 w/DR-ID601SE)
Classification Name:	Solid State X-ray Imager (Flat Panel/Digital Imager)
Regulations Number:	21 CFR 892.1650
Product Codes:	90 MQB
Device Class:	Class II
Review Panel:	Radiology
Common Name:	Flat Panel Digital Detector

I. INDICATIONS FOR USE

The Wireless/Wired FDR D-EVO flat panel detector system is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications wherever conventional film/screen or CR systems may be used. The FDR D-EVO is not intended for mammography, fluoroscopy, tomography, and angiography applications.

II. DEVICE DESCRIPTION

The proposed device, Wireless/Wired FDR D-EVO flat panel detector system, is a modified version of our currently-cleared predicate device, (wired) FDR D-EVO flat panel detector system (DR-ID600), K100762. The predicate device includes the flat panel sensor (DR-ID600SE), which provides only a wired communication mode. The

proposed device introduces a modified flat panel detector (DR-ID601SE), which provides both wired and wireless communication modes.

The indirect X-ray conversion method using GOS Scintillator, and FUJIFILM's unique Irradiated Side Sampling design, delivering high image quality, remained unchanged in the proposed device.

The proposed device is a portable digital detector system that acquires and digitizes x-ray exposures from standard radiographic systems, which is the same as the predicate device. The proposed device is designed to be used in any environment that would typically use a radiographic cassette. It can be placed in a wall bucky for upright exams, a table bucky for recumbent exams, or removed from the bucky for non-grid exams. All of which are also the same as the predicate device.

III. SUMMARY OF STUDIES

The Wireless/Wired FDR D-EVO flat panel detector system successfully completed internal and international IEC testing requirements. In addition, the FDA Draft Guidance Document, *Radio-Frequency Wireless Technology in Medical Devices*, issued on January 3, 2007 was followed for the wireless feature.

IV. SUBSTANTIAL EQUIVALENCE

The Wireless/Wired FDR D-EVO flat panel detector system is substantially equivalent to the predicate device, (wired) FDR D-EVO system (K100762). The proposed Wireless/Wired FDR D-EVO system has similar Indications for Use, functional and technical requirements as the currently-cleared predicate device, (wired) FDR D-EVO system (K100762). In addition, wireless communication specifications are substantially equivalent to the predicate Canon CXDI-70C Wireless (K102012).

V. CONCLUSION—

The Wireless/Wired FDR D-EVO flat panel detector system is substantially equivalent to the cleared predicate devices and conforms to applicable medical device safety standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Katherine Y. Choi, RAC
Regulatory Affairs Specialist
Fuji Medical Systems U.S.A., Inc.
419 West Avenue
STAMFORD CT 06902

AUG 23 2013

Re: K103596
Trade/Device Name: Wireless/Wired FDR D-EVO (DR-ID600 w/DR-ID601SE)
Flat Panel Detector System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: February 1, 2010
Received: February 2, 2010

Dear Ms. Choi:

This letter corrects our substantially equivalent letter of March 29, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103596

Device Name: Wireless/Wired FDR D-EVO (DR-ID600 w/DR-ID601SE) Flat Panel Detector System

Indications for Use:

The Wireless/Wired FDR D-EVO flat panel detector system is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications wherever conventional film /screen or CR systems may be used. The FDR D-EVO is not intended for mammography, fluoroscopy, tomography, and angiography applications.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103596